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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOC.	CONFIRMATION NO.
10/824,027	04/14/2004	Jennifer E. Van Eyk	PTQ-0053	6007
7590	08/09/2006			
Licata & Tyrrell P.C. 66 East Main Street Marlton, NJ 08053			ART UNIT 1653	FILE NUMBER

DATE MAILED:

8/09/2006

Please find below and/or attached an Office communication concerning this application pending.

<b>Office Action Summary</b>	<b>Application No.</b> 10/824,027	<b>Applicant(s)</b> EYK ET AL.	
	<b>Examiner</b> Anand U. Desai, Ph.D.	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 13-20 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 13-15 and 20 is/are rejected.
- 7) ☒ Claim(s) 16-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is in response to Amendment filed on May 15, 2006. Claims 2-12 have been cancelled previously. Claims 1, and 13-20 are currently pending and are under examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Withdrawal of Rejections**

3. The rejection of claims 1, and 16-18 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

4. The rejection of claims 1, 13, and 14 under 35 U.S.C. 102(b) as being anticipated by Mochly-Rosen (U.S. Patent 6,165,977) is withdrawn.

5. The rejection of claims 1, 13, 14, 15, 16, and 20 under 35 U.S.C. 102(b) as being anticipated by Currie et al. (Brain Research 863: 169-181 (2000)) is withdrawn.

6. The rejection of claims 1, 13, 14, 15, 16, 19, and 20 under 35 U.S.C. 102(b) as anticipated by Kobara et al. (J Mol. Cell Cardiol 28: 417-428 (1996)) is withdrawn.

7. The rejection of claims 1, 13, 14, 15, and 20 under 35 U.S.C. 103(a) as being unpatentable over Wang, Y. et al. (J. Mol. Cell. Cardiol. 33: 2037-2046 (2001)) is withdrawn.

**Maintenance of Rejections*****Claim Rejections - 35 USC § 103***

8. Claims 1, 13-15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (Journal of Neuroscience Research 67: 37-47 (2002)) in view of Nakagawa et al. (Neuroscience Letters 320: 33-36 (2002)).

Tanaka et al. describe the method of assessing the abundance of a preconditioning protein following the induction of a preconditioned state. Tanaka et al. describe the induction of gerbil forebrain preconditioning by bilateral carotid artery occlusion (see page 38, Materials and Methods, Animal model section). Tanaka et al. describe the detection of the modulation of preconditioning proteins, heat shock protein 40 (HSP40) and 70 (HSP70), using preconditioned gerbil hippocampal samples in a Western blot assay. Tanaka et al. describe the increase in levels of HSP40 and HSP70 protein in preconditioned gerbil hippocampal samples (see page 41, Figure 3 A, B, and C). Tanaka et al. does not describe the use of an agent to induce the precondition state of a cell, tissue or organ.

Nakagawa et al. describe the chemical preconditioning of gerbil hippocampal slices by administration of a neurotoxin inhibitor of succinate dehydrogenase, 3-nitropropionic acid (3-NPA) (see page 33, 2<sup>nd</sup> indented paragraph). Nakagawa et al. does suggest that the ischemic preconditioning is related to changes in heat shock protein (chaperone), Na<sup>+</sup>/K<sup>+</sup> ATPase or K<sub>ATP</sub> (see page 33, 1<sup>st</sup> indented paragraph, 3<sup>rd</sup> from last sentence). To describe the mimicry of 3-NPA and diazoxide during the 3-NPA chemical preconditioning process, Nakagawa et al. also describe the same extent of hypoxic tolerance of synaptic transmission due to 3-NPA or diazoxide (see Abstract, and page 34, 1<sup>st</sup> indented paragraph on left hand column, Group A, and

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C, and Figure 2A). Therefore, a person having ordinary skill in the art would have been motivated to use the agent 3-NPA as an inducer of preconditioning, because Nakagawa et al. have described preconditioning with a chemical agent, such as 3-NPA.

A person having ordinary skill in the art would have been motivated to measure the abundance of chaperone proteins, because Nakagawa et al. suggest the involvement of chaperone proteins during the preconditioning process. A person having ordinary skill in the art would have expected to succeed in detecting an increase (a form of modulation) in chaperone proteins to screen for preconditioning agents, because Tanaka et al. describe the increase in protein levels of HSP40 and HSP70 from preconditioned gerbil hippocampi. Therefore, it would have been obvious to the person having ordinary skill in the art to identify 3-NPA as an agent capable of inducing preconditioning a cell by assessing the ability of the agent to modulate the abundance of chaperone proteins, HSP40 and HSP70, because Tanaka et al. describes the increase in HSP40 and HSP70 in preconditioned hippocampi and Nakagawa et al. describes the preconditioning of hippocampi using 3-NPA, an inhibitor of mitochondrial protein succinate dehydrogenase (current application, claims 1, 13-15, and 20).

### *Claim Objections*

9. Claims 16-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*Conclusion*

10. No claims are allowed.

11. Applicant's amendment to remove the phrase "or event" to describe the preconditioned state necessitated the new ground(s) of rejections presented in this Office action, because the prior art of record was drawn to an event to induce preconditioning in a cell and the new art rejection is drawn to an agent to induce preconditioning. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

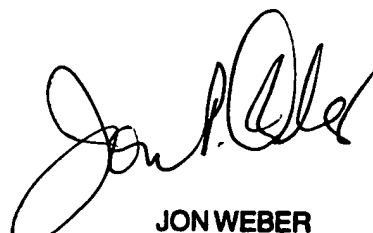
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 4, 2006



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**